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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------------------------------------------------------------------------|-------------|----------------------|-------------------------|------------------|
| 09/960,428 | 09/21/2001 | Harald Sobek | RDID00105US | 5555 |
| 23690 | 7590 | 05/24/2004 | EXAMINER | |
| Roche Diagnostics Corporation 9115 Hague Road PO Box 50457 Indianapolis, IN 46250-0457 | | | PATTERSON, CHARLES L JR | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1652 | |

DATE MAILED: 05/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------------------|------------------------------|--|
| Office Action Summary | Application No. 09/960,428 | Applicant(s) SOBEK ET AL. | |
| | Examiner Charles L. Patterson, Jr. | Art Unit 1652 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/19/02, 4/2/02 and 8/13/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The specification does not contain a Brief Description Of The Drawings, as required by 37 CFR § 1.74.

Claims 1, 11, 13, 15, 16, 18, 20 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 15, 20 and 21 are indefinite in the recitation of "AMV-RT".

Abbreviations should be avoided in patent application and should be defined in at least the first claim in which they are mentioned. A recitation of "Avian Myeloblastosis Virus-Reverse Transcriptase (AMV-RT) on line 1 of claim 1 would overcome this rejection.

Claims 1 and 16 are also indefinite in the recitation of "and/or" on line 4. It is not known whether the limitation is meant to be cumulative or alternative.

Claim 1 is confusing and apparently incorrect in the recitation of "transformed in" on lines 6-7. Apparently the recitation should be "transformed into".

Claim 11 is indefinite in that there is no antecedent basis for "the tryptophan tRNA".

Claim 13 is indefinite in the recitation of "GroEL and GroES, DnaK and DnaJ, GrpE and/or ClpB". It is impossible to tell how many of the 6 genes are meant to be expressed.

Claim 18 is confusing and indefinite in the recitation of "expressed in a prokaryotic host cell". It is not clear whether the prokaryotic cells of claim 1 are intended or some unrelated cell.

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Claim 21 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, ~~concise, and exact terms as to enable any person skilled in the art to~~ which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It appears from a reading of the specification that a helper plasmid must be used in order to express the α and β genes. pAMV- α_{lacIq} and pAMV- β_{dnaY} are the expression plasmids used to express AMV- α and AMV- β , with the lacIq and dnaY expression cassettes coming from the helper plasmids (examples 2 and 3). These combinations were shown to produce an active reverse transcriptase (Figure 1). This is the apparent difference in the results of Swaminathan (5), where they apparently obtained 90% insoluble component and the instant application (see page 25, lines 19-20 of Swaminathan). Therefore the instant claims should be limited to the embodiments shown in the specification to produce active enzymes.

E. coli LE392 pAMV $\alpha\beta$ -4+pCHAP-5 cells described in Example 6 might be shown to produce an active reverse transcriptase but this is not fully understood. Figure 3 is purported to shown this activity but lanes 2, 4 and 5

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shown increasing amounts of "amplification product", yet they have decreasing amounts of product. An explanation is required.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Swaminathan (5) or Muller, et al. (25).

Swaminathan teach the cloning of the genes for Avian Myeloblastosis Virus reverse transcriptase into *E. coli* and the expression of an active enzyme. While it is true that page 25, lines 19-20 teach about "90% of the expressed protein was found in inclusion bodies", there was produced 10% that was soluble. It is noted that the instant claims do not require a soluble enzyme and that there nothing teaching that the enzyme present in the inclusion bodies did not have activity. It would have been obvious to one of ordinary skill in the art to use the methods taught by Swaminathan to clone AMV RT with at least a reasonable expectation of success. The requirements of the dependent claim would have been obvious to one of ordinary skill, absent convincing proof to the contrary.

Muller, et al. teach the cloning of the heterodimer of HIV reverse transcriptase into *E. coli* and the production of an active product. Since it is known that HIV reverse transcriptase is a heterodimer like AMV RT, it would have been obvious to one of ordinary skill in the art to use the methods taught by the instant reference to clone AMV RT with at least a reason-

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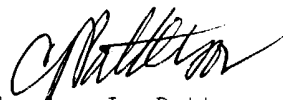
able expectation of success since both enzymes are heterodimers. The requirements of the dependent claim would have been obvious to one of ordinary skill, absent convincing proof to the contrary.

It is noted that the priority date of this application may not be relied on to overcome a rejection because a sworn translation has not been submitted.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
May 21, 2004